NEXPLANON® (etonogestrel implant): A Subdermal Implant With Efficacy Up to 3 Years[a]

[a]NEXPLANON must be removed by the end of the third year and may be replaced by a new NEXPLANON at the time of removal, if continued contraceptive protection is desired.

NEXPLANON is indicated for use by women to prevent pregnancy.

SELECTED SAFETY INFORMATION

Who is not appropriate for NEXPLANON

- NEXPLANON should not be used in women who have known or suspected pregnancy; current or past history of thrombosis or thromboembolic disorders; liver tumors or active liver disease; undiagnosed abnormal genital bleeding; known or suspected breast cancer, personal history of breast cancer, or other progestin-sensitive cancer now or in the past; or allergy to any component of NEXPLANON.

WARNINGS and PRECAUTIONS

Complications of insertion and removal

- Palpate immediately after insertion to ensure proper placement. Undetected failure to insert the implant may lead to unintended pregnancy.
- Insertion and removal-related complications may include pain, paresthesias, bleeding, hematoma, scarring, or infection. If NEXPLANON is inserted too deeply (intramuscular or in the fascia), neural or vascular injury may occur. Implant removal may be difficult or impossible if the implant is not inserted correctly, inserted too deeply, not palpable, encased in fibrous tissue, or has migrated. If at any time the implant cannot be palpated, it should be localized and removed.
- There have been postmarketing reports of implants located within the vessels of the arm and the pulmonary artery; in these cases, endovascular or surgical procedures may be needed for removal.
- Failure to remove the implant may result in continued effects of etonogestrel, such as compromised fertility, ectopic pregnancy, or persistence or occurrence of a drug-related adverse event.

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NOTE: This slide must be presented.

NEXPLANON® (etonogestrel implant): Selected Safety Information Indication and Warnings and Precautions

Selected Safety Information *(continued)*

WARNINGS and PRECAUTIONS (*continued*)

NEXPLANON® (etonogestrel implant) and pregnancy

- Should pregnancy or lower abdominal pain occur while using NEXPLANON, be alert to the possibility of an ectopic pregnancy.
- **Rule out pregnancy before inserting NEXPLANON.**

Educate her about the risk of serious vascular events

- There have been postmarketing reports of serious arterial thrombotic and venous thromboembolic events, including cases of pulmonary emboli (some fatal), deep vein thrombosis, myocardial infarction, and strokes, in women using etonogestrel implants. Assess women with known risk factors. NEXPLANON should be removed if thrombosis occurs.
- NEXPLANON should not be used prior to 21 days postpartum due to risk of thromboembolism.
- Women with a history of thromboembolic disorders should be made aware of the possibility of a recurrence.
- In case of long-term immobilization, consider removing NEXPLANON.

Counsel her about changes in bleeding patterns

- Women are likely to have changes in their menstrual bleeding pattern with NEXPLANON, including changes in frequency, intensity, or duration. Evaluate abnormal bleeding as needed to exclude pathologic conditions or pregnancy. In clinical studies of the non-radiopaque etonogestrel implant, the most common reason for discontinuation was changes in bleeding patterns (11.1%).

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NOTE: This slide must be presented.

NEXPLANON® (etonogestrel implant): Selected Safety Information
Warnings and Precautions

Selected Safety Information *(continued)*

WARNINGS and PRECAUTIONS (*continued*)

Be aware of other serious complications, adverse reactions, and drug interactions

- Remove NEXPLANON® (etonogestrel implant) if jaundice occurs or blood pressure rises significantly and becomes uncontrolled.
- Monitor prediabetic and diabetic women using NEXPLANON.
- Observe women with a history of depressed mood. Consider removing NEXPLANON in patients who become significantly depressed.
- The most common adverse reactions (≥10%) reported in clinical trials were headache (24.9%), vaginitis (14.5%), weight increase (13.7%), acne (13.5%), breast pain (12.8%), abdominal pain (10.9%), and pharyngitis (10.5%).
- Drugs or herbal products that induce enzymes, including CYP3A4, may decrease the effectiveness of NEXPLANON or increase breakthrough bleeding.
- The efficacy of NEXPLANON in women weighing more than 130% of their ideal body weight has not been studied. Serum concentrations of etonogestrel are inversely related to body weight and decrease with time after implant insertion. NEXPLANON may be less effective in overweight women.
- NEXPLANON does not protect against HIV or other STDs.

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NOTE: This slide must be presented.

NEXPLANON® (etonogestrel implant): Selected Safety Information
Warnings and Precautions